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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,413	04/21/2008	Mark G Palermo	33727-US-PCT	1934
75/074	75/90	02/01/2011		
NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 220 MASSACHUSETTS AVENUE CAMBRIDGE, MA 02139				
EXAMINER				
NIEBAUER, RONALD T				
ART UNIT		PAPER NUMBER		
1654				
NOTIFICATION DATE		DELIVERY MODE		
02/01/2011		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/594,413

**Applicant(s)**

PALERMO ET AL.

**Examiner**

RONALD T. NIEBAUER

**Art Unit**

1654

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-24 and 26-38 is/are pending in the application.
- 4a) Of the above claim(s) 22-24, 26 and 30-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21 and 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/26/06; 7/15/10
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Based on the claim amendments, the restriction requirement is modified such that original groups 1-69 are combined to a single group. As such, claims 21,24,26-38 are drawn to compounds (new group I). Claims 22-23 (original group 70) are drawn to methods of treating diseases (new group II). The election of species as set forth in the previous restriction requirement still applies. The groups do not relate to a single invention for the reasons set forth in the previous restriction requirement.

Applicant's election with traverse of group I (claims 21,24,26-38) and the species of compound as shown in example 45 in the reply filed on 1/3/11 is acknowledged. The traversal is on the ground(s) that many of the compounds have a common core and the search would not require an undue burden.

Applicants arguments have been considered but are not found persuasive.

Although applicants argue that many of the compounds have a common core and the search would not require an undue burden as set forth in the restriction requirement and 102 rejection below the claims lack the same or corresponding technical feature and thus lack unity. Further, the search of the various species would require employing different search queries and the prior art applicable to one species would not likely be applicable to another species.

The requirement is still deemed proper and is therefore made FINAL.

Applicants elected species was found to be free of the prior art. However, no claim reads solely on the elected species. In accord with MPEP 803.02 the search was extended to the extent

necessary to determine patentability of the Markush-type claim. As discussed in the 102 rejection art was found that reads on the Markush-type claim. In accord with MPEP 803.02 the search is not extended unnecessarily to all species.

Claims 1-20,25 have been cancelled.

Claims 22-23 are to a non-elected group.

Claims 22-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/3/11.

Claims 24,26, 30-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/3/11.

Claims 21,27-29 are under consideration.

### **Information Disclosure Statement**

The information disclosure statement filed 7/15/10 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because 37 CFR 1.98(b)(5) states that each publication must be identified by a date. In the instant case the first npl of the 7/15/10 does not include a date and thus is not compliant with 37 CFR 1.98(b)(5). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission

for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

In the instant case, the IDS of 9/26/06 lists various references. However, no copies of any of the references has been provided. Thus the IDS is not compliant with 37 CFR 1.98(a)(2).

### **Claim Objections**

Claim 27 is objected to because of the following informalities:

In claim 27 there are numerous occurrences of the phrase 'n is'. In certain locations the phrase is 'n is 0' (i.e. n is zero) and at other location the phrase is 'n is O' (i.e. n is the letter O). It is clear from the context from the claim that n is a number not a letter.

Appropriate correction is required.

### **Specification**

The disclosure is objected to because of the following informalities: page 114 of the specification refers to 'Table 1'. However, there is no table identified as table 1. It is noted that on page 35 of the reply of 1/3/11 that applicants make remarks about the specification. A remark is separate and distinct from an amendment. Thus the remarks have not been incorporated into the specification.

The specification page 114 line 2 refers to AVPFAQK. 37 CFR 1.821 requires that amino acids of 4 or more specific amino acids must be included in a sequence listing and shall be preceded by an appropriate sequence identifier.

Appropriate correction is required.

### **Priority**

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or

more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/560,186 (4/7/04), fails to provide adequate written description in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

In the instant case, claim 27 and dependent claims refer to the variable D which is described as N(Rh) or S(O) or S(O)<sub>2</sub> for example.

#### Lack of Ipsis Verbis Support

Application No. 60/560,186 is void of support for compounds where D is N(Rh) or S(O) or S(O)<sub>2</sub> for example.

#### Lack of Implicit or Inherent Support

Section 2163 of the MPEP states: 'While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure'.

Although the above statement is with respect to new claim limitations, the analysis is similar in determining conditions for receiving the benefit of an earlier filing date.

Application No. 60/560,186 recites that D can be -CO- (page 5). However, -CO- is not the equivalent of nor suggestive of N(Rh) or S(O) or S(O)<sub>2</sub> for example.

From the disclosure of Application No. 60/560,186 there is nothing to lead one to the genus of compounds as instantly claimed. As such, one would not conclude that Application No. 60/560,186 provides adequate support for the instant claims.

It is noted that section 706.02 VI D of the MPEP sets forth the method to determine the effective filing date. In particular, 'If the application properly claims benefit under 35 U.S.C. 119(e) to a provisional application, the effective filing date is the filing date of the provisional application for any claims which are fully supported under the first paragraph of 35 U.S.C. 112 by the provisional application.'. In the instant case, none of the claims under examination are fully supported by the provisional Application No. 60/560,186. As such, none of the claims under examination receive the benefit of the provisional application. It is noted that claims are either fully supported or not fully supported. In other words, claims are not treated as 'supported in part' even though one particular element may be supported in the provisional application. As such, for purposes of searching for prior art, a priority date of 4/6/05 is used for the instant claims under examination.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

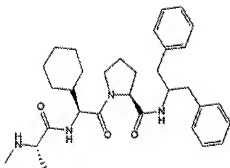
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



**Claims 21,27-29** are rejected under 35 U.S.C. 102(b) as being anticipated by Sharma et al (WO 2004/005248).

It is noted that WO 2004/005248 was cited with IDS 9/26/06. However, no copy of the document was provided. A copy of WO 2004/005248 is included with this office action.

Sharma teach IAP inhibitors (abstract). Sharma teach specific compounds including those in examples 10,15-16 (see pages 17-18). Sharma teach the compounds with carriers and in effective amounts (claim 7). In relation to the instant claims, example 16 of Sharma



meets the structural limitations of claims 27-29 since R1 is methyl, R2 is H, R3 is methyl, R4 is C6 cycloalkyl, R5 is H, R6,R6',R7,R7' are H, n is 0, Rd is Ar1-D-Ar2 where Ar1 is substituted phenyl (substituted with C(O)-NH-CH-CH2), D is C1 alkyl and Ar2 is phenyl. Since Sharma teach the compounds with carriers and in effective amounts (claim 7) the limitations of claim 21 are met.

#### **Prior art of record**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Cohen et al (US 20060167066 as cited in IDS 7/15/10) teach IAP inhibitors including compounds 60,75 (pages 20-21).

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/  
Supervisory Patent Examiner, Art Unit 1654

/Ronald T Niebauer/  
Examiner, Art Unit 1654

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